

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

REC'D 27 MAY 2005

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To:

see form PCT/ISA/220

6/8

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2005/001457

International filing date (day/month/year)  
18.01.2005

Priority date (day/month/year)  
16.01.2004

International Patent Classification (IPC) or both national classification and IPC  
G01K3/04

Applicant  
UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INC.

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/001457

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/001457

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, Inventive step or  
Industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1,3-8,10-21
	No: Claims	2,9,22
Inventive step (IS)	Yes: Claims	
	No: Claims	1-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item VIII**

**Certain observations (Clarity)**

1 The application does not meet the requirements of Article 6 PCT, because **claims 1, 2, 16, 21, 22** are not clear.

1.1 Although **claims 1, 2** have been drafted as separate independent claims in the same category, they appear to relate effectively to the same subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT. The same holds for the independent use **claims 21, 22**.

**Claims 1, 2, 21, 22** are therefore not clear (Article 6, PCT).

1.2 Furthermore, **claim 1** describes a TTI system comprising (multiple) time temperature integrators, all having a zero-order decay reaction rate mechanism according to the same equation. The application (description: page 15, lines 7-11), however, describes a system with two TTI's having different reaction rate mechanisms. **Claim 1** is therefore not supported by the description.

1.3 The clarity problem in **claim 16** relates to points c) and d) of the method. For the skilled person, it is not clear how safety of fresh food can be monitored by observing and comparing the *rates* of change of the TTI's.

In the description (page 10, line 36 - page 11, line 6) is suggested that not only the rate of change is observed, but also the change itself. Further, in the passage cited above, only the changes (and not the rates) are compared in order to monitor food safety. This interpretation is confirmed on page 15 (lines 19-35).

In conclusion, **claim 16** in its present form (i.e. comparing rates of changes) is not supported by the description and is therefore not clear (Article 6, PCT). In the rest of this Written Opinion it is assumed that in **claim 16**, the change (instead of the rate of change) is observed and compared.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**Documents**

2 Reference is made to the following documents:

D1: US-A-6 113 857 (MANICO ET AL) 5 September 2000

D2: WELT B A, SAGE D S, BERGER K L: "Performance Specification of Time-temperature Integrators Designed to Protect Against Botulism in Refrigerated Fresh Foods" JOURNAL OF FOOD SCIENCE, vol. 68, no. 1, 2003, pages 2-9, XP002328450

D3: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; September 1998 (1998-09), SKINNER GUY E ET AL: "Conservative prediction of time to Clostridium botulinum toxin formation for use with time-temperature indicators to ensure the safety of foods" XP002328442 Database accession no. PREV199800447221

**Novelty**

3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 2, 9, 22** is not new in the sense of Article 33(2) PCT.

3.1 Document D1 discloses (the references in parentheses applying to this document):

An improved fresh food and perishable products monitoring system comprising time temperature integrators comprising a reaction rate mechanism having a reaction rate constant (Col.1, lines 13-18; Col.2, lines 17-24);  
wherein the reaction rate mechanism exhibits temperature sensitivity (Col.2, lines 19-21);  
wherein the reaction rate mechanism decays when exposed to temperature (Col.4, lines 3-9);

wherein the improvement comprises a reaction rate mechanism approximated by reaction kinetic schemes (Col.7, lines 26-34).

The subject-matter of **claim 2** and, mutatis mutandis, independent use **claim 22** is therefore not new (Article 33(2) PCT).

**3.2 Document D1 discloses further:**

a system of time temperature integrators wherein the TTI's have different temperature sensitivities (Col.2, lines 19-21) as in **claim 9**.

The subject-matter of **claim 9** is therefore not new (Article 33(2) PCT).

**Inventive Step**

- 4 The above-mentioned lack of clarity notwithstanding, the subject-matter of **claims 1, 3-8, 10-21** does not involve an inventive step in the sense of Article 33(3) PCT, and therefore the criteria of Article 33(1) PCT are not met.

**INDEPENDENT CLAIMS**

- 4.1 The reaction rate mechanism according to the equation given in **claim 1** is known from document D2 (see the paragraph on "Predictive modelling"). A system of multiple TTI's is described in document D1 (see the passages cited in the corresponding Search Report). The subject matter of **claim 1** (and independent use **claim 21**) is therefore anticipated by the combination of D1 and D2 and does not involve an inventive step (Article 33(3) PCT).
- 4.2 Independent method **claim 16** (referring back to **claim 1**) is also anticipated by the combination of D1 (comparing the readings from multiple TTI's: Col.7, lines 19-25) and D2 (i.e. the TTI described in **claim 1**). The subject matter of **claim 16** therefore does not involve an inventive step (Article 33(3) PCT).

**DEPENDENT CLAIMS**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/001457

- 4.3 Dependent **claims 3-8, 10-15, 17-20** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D1-D3 and the corresponding passages cited in the search report.

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For further options, see Form PCT/ISA/220.

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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/001457

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**Box No. I Basis of the opinion**

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  - a. type of material:
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4. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/001457

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**Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, Inventive step or Industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1,3-8,10-21
	No: Claims	2,9,22
Inventive step (IS)	Yes: Claims	
	No: Claims	1-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Box No. VIII Certain observations on the International application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item VIII**

**Certain observations (Clarity)**

1 The application does not meet the requirements of Article 6 PCT, because **claims 1, 2, 16, 21, 22** are not clear.

1.1 Although **claims 1, 2** have been drafted as separate independent claims in the same category, they appear to relate effectively to the same subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT. The same holds for the independent use **claims 21, 22**.

**Claims 1, 2, 21, 22** are therefore not clear (Article 6, PCT).

1.2 Furthermore, **claim 1** describes a TTI system comprising (multiple) time temperature integrators, all having a zero-order decay reaction rate mechanism according to the same equation. The application (description: page 15, lines 7-11), however, describes a system with two TTI's having different reaction rate mechanisms. **Claim 1** is therefore not supported by the description.

1.3 The clarity problem in **claim 16** relates to points c) and d) of the method. For the skilled person, it is not clear how safety of fresh food can be monitored by observing and comparing the *rates* of change of the TTI's.

In the description (page 10, line 36 - page 11, line 6) is suggested that not only the rate of change is observed, but also the change itself. Further, in the passage cited above, only the changes (and not the rates) are compared in order to monitor food safety. This interpretation is confirmed on page 15 (lines 19-35).

In conclusion, **claim 16** in its present form (i.e. comparing rates of changes) is not supported by the description and is therefore not clear (Article 6, PCT). In the rest of this Written Opinion it is assumed that in **claim 16**, the change (instead of the rate of change) is observed and compared.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

**Documents**

2 Reference is made to the following documents:

D1: US-A-6 113 857 (MANICO ET AL) 5 September 2000

D2: WELT B A, SAGE D S, BERGER K L: "Performance Specification of Time-temperature Integrators Designed to Protect Against Botulism in Refrigerated Fresh Foods" JOURNAL OF FOOD SCIENCE, vol. 68, no. 1, 2003, pages 2-9, XP002328450

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**Novelty**

3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 2, 9, 22** is not new in the sense of Article 33(2) PCT.

3.1 Document D1 discloses (the references in parentheses applying to this document):

An improved fresh food and perishable products monitoring system comprising time temperature integrators comprising a reaction rate mechanism having a reaction rate constant (Col.1, lines 13-18; Col.2, lines 17-24);  
wherein the reaction rate mechanism exhibits temperature sensitivity (Col.2, lines 19-21);  
wherein the reaction rate mechanism decays when exposed to temperature (Col.4, lines 3-9);

wherein the improvement comprises a reaction rate mechanism approximated by reaction kinetic schemes (Col.7, lines 26-34).

The subject-matter of **claim 2** and, mutatis mutandis, independent use **claim 22** is therefore not new (Article 33(2) PCT).

**3.2 Document D1 discloses further:**

a system of time temperature integrators wherein the TTI's have different temperature sensitivities (Col.2, lines 19-21) as in **claim 9**.

The subject-matter of **claim 9** is therefore not new (Article 33(2) PCT).

**Inventive Step**

- 4 The above-mentioned lack of clarity notwithstanding, the subject-matter of **claims 1, 3-8, 10-21** does not involve an inventive step in the sense of Article 33(3) PCT, and therefore the criteria of Article 33(1) PCT are not met.

**INDEPENDENT CLAIMS**

- 4.1 The reaction rate mechanism according to the equation given in **claim 1** is known from document D2 (see the paragraph on "Predictive modelling"). A system of multiple TTI's is described in document D1 (see the passages cited in the corresponding Search Report). The subject matter of **claim 1** (and independent use **claim 21**) is therefore anticipated by the combination of D1 and D2 and does not involve an inventive step (Article 33(3) PCT).
- 4.2 Independent method **claim 16** (referring back to **claim 1**) is also anticipated by the combination of D1 (comparing the readings from multiple TTI's: Col.7, lines 19-25) and D2 (i.e. the TTI described in **claim 1**). The subject matter of **claim 16** therefore does not involve an inventive step (Article 33(3) PCT).

**DEPENDENT CLAIMS**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

**PCT/US2005/001457**

- 4.3 Dependent **claims 3-8, 10-15, 17-20** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see documents D1-D3 and the corresponding passages cited in the search report.